

# **GUIDELINES FOR THE NHS**

In support of the Memorandum of Understanding

Investigating patient safety incidents involving unexpected death or serious untoward harm: a protocol for liaison and effective communications between the National Health Service, Association of Chief Police Officers and the Health & Safety Executive

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## Purpose of NHS guidelines

1. The guidelines should be read in conjunction with the Memorandum of Understanding (MOU) *Investigating patient safety incidents involving unexpected death and serious untoward harm: a protocol for liaison and effective communications between the National Health Service, Association of Chief Police Officers and Health & Safety Executive*. This was published on the 20th February 2006. and can be found at Available at:  
[http://www.dh.gov.uk/PublicationsAndStatistics/Publications/PublicationsPolicyAndGuidance/PublicationsPolicyAndGuidanceArticle/fs/en?CONTENT\\_ID=4129918&chk=P5hkFZ](http://www.dh.gov.uk/PublicationsAndStatistics/Publications/PublicationsPolicyAndGuidance/PublicationsPolicyAndGuidanceArticle/fs/en?CONTENT_ID=4129918&chk=P5hkFZ)
2. These guidelines provide practical advice to NHS organisations about what to do when faced with a patient safety incident or incidents that may require investigation by the police and/or Health & Safety Executive (HSE). They provide information about:
  - Scope of the memorandum of understanding including the definition of an NHS patient
  - Identifying incidents
  - Investigating incidents and making a referral
  - Preserving and safeguarding evidence
  - Conduct and management of the Incident Coordination Group
  - Sharing information
  - Supporting patients, relatives and NHS staff
  - Handling communications/media
3. The guidelines set out what is considered to be good practice when dealing with patient safety incidents. They have been produced in consultation with other organisations including the police, HSE and the National Patient Safety Agency (NPSA).

The appendices contain guidance about:

- Definitions of key terms relating to offences
  - Roles, responsibilities of the police and the HSE
  - The role and contact details of other organisations that may become involved in patient safety incidents
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- There are also model documents to aid NHS staff, police officers and HSE inspectors run an Incident Coordination Group.
4. The MOU encourages co-operation between the various agencies involved in investigating serious incidents in the NHS. To this end, NHS organisations<sup>1</sup> are encouraged to co-operate as fully as possible in investigations by other agencies, and should, for example, provide necessary documents as soon as appropriate.
  5. NHS organisations should make sure they are familiar with patient safety procedures and reporting arrangements as developed by the Department of Health (DH) and the National Patient Safety Agency. It is important that the requirements of these procedures and reporting arrangements are followed and, where necessary, discussed with the police and the HSE at the outset of any investigation(s).
  6. Police officers have access to the ACPO Murder Investigation Manual that contains advice about the conduct of police investigations in healthcare settings. This advice is consistent with these guidelines. HSE inspectors also have access to their own internal guidance.
  7. The intention is that the guidelines should be developed in the light of experience. To that end, feedback on their practical application can be provided to the Patient Safety and Investigations Branch (PS&I) via the Department of Health website.

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<sup>1</sup> This will include NHS Trusts, Primary Care Trusts (PCTs), Foundation Trusts and NHS patients being treated in independent healthcare sector hospitals.

8. The development group will send out a questionnaire a year or so after the launch of the MOU protocol. The DH will take the opportunity to ask for feedback from the NHS on the guidelines. Also if there are any queries on the guidelines the NHS could contact PS&I and also to inform them of any changes they wish to suggest, at the following address: [memorandumofunderstanding@dh.gsi.gov.uk](mailto:memorandumofunderstanding@dh.gsi.gov.uk)

#### Definition of an NHS patient

9. For the purposes of the MOU protocol and these guidelines an NHS patient is defined as:

*‘A person receiving care or treatment under the NHS Act 1977.’*

10. In practical terms this generally means NHS-funded patients on NHS premises, and includes NHS patients being cared for in non-NHS premises or where patients/people other than NHS patients are on NHS premises, the expectation is that the spirit of the Memorandum of Understanding will apply.

#### Private patients on NHS premises and independent providers

11. The principles of the MOU will apply to private patients on NHS premises. The provisions of the MOU protocol along with these guidelines will form part of the contractual agreement between the NHS and independent healthcare providers in the future.

## Investigating incidents

12. The NHS is developing ever more rigorous methods for investigating incidents resulting in harm or those that could have harmed a patient. This work is being led by the Department of Health and the NPSA and both are committed to promoting a culture of openness and fairness in the NHS. Investigating methods such as root cause analysis have been developed and the NPSA is helping the NHS to build its capacity to target underlying systems failures that have been found to lie at the root of many patient safety incidents. This work is based on research that shows that the best way of reducing error rates is to target the underlying systems failures, rather than take action against individual members of staff. Most patient safety incidents in the NHS can be dealt with properly by these procedures. There will be occasions when the NHS will need to refer matters to the police. However, the NHS also must be able to respond promptly to referrals brought to the attention of the police from other sources, including patients, relatives, carers, staff and coroners.
  
13. Where appropriate, patient safety incidents should be investigated using existing NHS procedures as developed by the Department of Health and the National Patient Safety Agency. Depending on their nature, incidents should also be reported by NHS organisations to other health-related organisations with an investigative function. The investigative functions of these bodies include medical devices/equipment, individuals, organisations and systems.
  - Medicines Healthcare products Regulatory Agency (MHRA)
  - NHS Estates (part of the NPSA)
  - Healthcare Commission
  - NHS Counter Fraud & Security Management Service (CFSMS)
  - Professional regulatory bodies e.g. General Medical Council, Nursing & Midwifery Council

14. NHS organisations should as necessary also inform organisations with an advisory or analytical function such as:
  - Department of Health - Patient Safety & Investigations Branch
  - Serious Hazards of Transfusion (SHOT)
  - Health Protection Agency (HPA)
  - National Patient Safety Agency (to whom all incidents must be reported)
  - NHS Litigation Authority
  - National Confidential Enquiries
  - Strategic Health Authority
  - Monitor (for Foundation Trusts)
  
15. Further details about these organisations are to be found in Appendix C along with website addresses and contact information. If necessary, NHS organisations can also seek advice from the Department of Health's Patient Safety & Investigation Branch [see contact details at paragraph 8] and/or the Healthcare Commission.
  
16. NHS organisations have the legal responsibility to ensure the security of patients and staff. This work is overseen nationally by the CFSMS. Locally, this is the responsibility of the Security Management Director (SMD) and the Local Security Management Specialist (LSMS). If, during the course of an investigation of patient safety, any incidents come to light concerning poor security, the LSMS must be notified as soon as practicable.

#### Making a referral to the police and/or HSE

17. There will be occasions when the NHS will need to refer matters to the police; NHS organisations may need to consider whether a safety incident should be reported to the police and/or HSE. In these circumstances, it is best practice to make early contact with the police and/or HSE to discuss concerns and to take their advice on further

action. The NHS organisation's risk manager or equivalent person with risk management responsibility, with the agreement of the chief executive or nominated representative, should take responsibility for ensuring that this advice is sought and, if necessary, a referral made. The roles, responsibilities and working practices of the police and HSE are described in more detail in Appendix B.

18. It is impossible to present a comprehensive list of examples that may prompt an NHS organisation to consider a referral. Most incidents are investigated by the NHS; therefore circumstances should be sufficiently serious and criminal intent suspected to warrant a police investigation. This decision should be taken by an appropriately senior person, preferably at executive level in the organisations. The general criteria set at paragraph 2.7 (page seven) of the MOU protocol should guide this decision making.
19. Unexpected deaths and/or incidents resulting in serious untoward harm to patients may be reported by NHS organisations to the HSE under the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995 (RIDDOR). RIDDOR places a legal duty on employers and those in control of premises to report some work-related accidents, diseases and dangerous occurrences to the relevant enforcing authority for their work activity. For the NHS, this is usually the HSE.
20. Accidents to patients that arise from medical treatment or diagnosis in the main are exempt from this requirement. The HSE does not investigate all accidents, but it will normally investigate all fatal accidents under RIDDOR. Such incidents may also be referred to the HSE by the police or via the coroner. In all these circumstances a criminal investigation may be launched by the HSE and this will be conducted according to the Memorandum of Understanding to which these guidelines refer.

21. The law requires the following work-related incidents to be reported:
- Deaths
  - Major injuries
  - Over-three day injuries - where an employee or self-employed person has an accident and the person is away from work or unable to work normally for more than three days
  - Injuries to members of the public where they are taken to hospital
  - Work-related diseases
  - Dangerous occurrences - where something happens that does not result in a reportable injury but which could have done
22. The matter of when and what to report to the HSE should be discussed with the NHS organisation's risk manager or equivalent in the first instance. Further advice should be sought from the HSE's Incident Contact Centre on 0151 922 9235 in the first instance or reference can be made to the HSE or RIDDOR website ([www.riddor.gov.uk](http://www.riddor.gov.uk)) and a RIDDOR reporting form (F2508) can filled out and submitted online.
23. At the point of referral the NHS organisation's risk manager, or another appropriately qualified individual should take responsibility for preserving any relevant evidence and, if appropriate, safeguarding the scene.

#### **Case Study 1**

Mrs R, an 89-year-old widow was admitted to a small district general hospital on 1 February 2000 via the accident & emergency department after a fall at home, where she lived independently with some social services support.

She had broken her leg and needed an operation and a Thompson's arthroplasty was carried out on 2 February. Mrs R recovered well immediately after the operation. She was starting to move around with the help of regular physiotherapy.

On the morning of 7 February a nurse tending to a patient in the bed next to Mrs R's noticed that she was struggling for breath, retching / regurgitating and was drowsy. The nurse went to Mrs R who looked pale and clammy. Mrs R needed suction to her airway but the suction unit above the bed did not work when turned on. A suction unit was brought from a nearby bed, but tubing was missing from it. The staff managed to create some suction from the unit at Mrs R's bed, but her condition did not improve, so a crash call was put out. The team attended as Mrs R suffered a respiratory arrest; shortly afterwards she suffered a cardiac arrest. Efforts to

resuscitate her failed.

There had been a clinical situation involving emergency equipment two weeks earlier. It was unusual for suction units to be out of order so the possibility that someone had tampered with them was considered. The ward manager contacted the senior manager and risk manager. After discussion with the clinical director, they called the police. The senior manager ensured that the scene remained undisturbed and that no one entered the area. The police examined the scene and talked to nursing staff. Officers were satisfied that there was no evidence of tampering. The officers were impressed that the scene had been left undisturbed because it was a potential crime scene.

The HSE and the Medical Devices Agency (now the MHRA) were informed.

The senior manager reported the incident in line with the trust's patient safety/incident policy and procedure and a full root cause analysis took place.

**Points to note:**

- *Two incidents of potential tampering with suction equipment prompted the trust to alert the police, the HSE and the MHRA*
- *The scene of the incident was left undisturbed in order to secure & preserve any evidence*
- *The incident was reported within the trust and subsequently investigated using root cause analysis*
- *The findings were shared across the trust and improvements put in place to minimise the likelihood of a similar incident.*

### Conducting NHS investigations

24. Careful consideration needs to be given to the conduct of any NHS investigation once a matter has been referred to the police and/or HSE. Immediate patient and staff safety should be assured but further investigation should take place only after the first meeting of the Incident Coordination Group which should be called promptly i.e. within 5 days see paragraph 37 of these guidelines. At this point the need for an NHS investigation should be discussed with the police and/or HSE and an agreement reached about when and how this is to be conducted. The service provider should also inform the PCT or SHA about the incident.

25. The risks of conducting an NHS investigation between referral to the police and/or HSE and the first meeting of the Incident Coordination Group are that the conduct of other investigations by the other organisation may be compromised.
  
26. The primary concern of all agencies is that of public safety. While there is nothing in law that says the police's duty to investigate ranks higher than the NHS's duty to ensure patient safety, interference with a police investigation could undermine potential legal proceedings. However, where the NHS considers its own investigation to be particularly important, it should not be slow to challenge any decisions or requests by the police that an investigation should not be undertaken by the NHS. In many cases, the discussion at ICG should be used to find a way forward for the NHS to meet its patient safety obligations without compromising the police investigation. In all cases, the NHS must ensure that serious incidents are reported within the NHS according to the current guidance. Any request by the police for the NHS organisation involved not to discuss the incident with others can never override the NHS organisation's obligations to do this. Case-by-case judgements need to be reached with the police at the Incident Coordination Group about the timing, the scope of and limits of any NHS investigation.
  
27. There is no obligation on the police to allow the NHS to work alongside them, but in certain circumstances it may be worthwhile and beneficial for both organisations to do so - particularly where matters of a complex nature are being investigated. The possibility of joint investigations should be considered at the meeting of the Incident Coordination Group. When a joint investigation is proposed, it is important to establish at the outset which organisation is taking the lead.

## Preserving evidence and safeguarding the scene

28. In the immediate aftermath of a patient safety incident steps need to be taken to secure and preserve evidence. This may be particularly true of busy NHS clinical areas that are in constant use by patients and staff and when people are following routine NHS operational practice e.g. sterilising equipment after a procedure or operation.
29. The availability of physical, scientific and documentary evidence may be critical to understanding what has happened and to the conduct of a satisfactory investigation by any agency. Destruction of evidence may also delay putting safety measures in place. It may also lead to a more protracted and complex investigation than would otherwise have been necessary.
30. It is especially important where a criminal offence is suspected that evidence is retained, since failure to do so may mean that legal proceedings are undermined.
31. Some healthcare incidents only come to light some time after the event(s). In this case, the evidence may be less easy to identify and locate. However, the same sort of approach as outlined below should also be followed.
32. The following practical steps should be taken by an NHS organisation in their efforts to preserve and safeguard evidence - including long after the event. If in doubt about how to do this, seek the advice of the police and/or HSE. The practical steps are divided into three distinct phases: assessment, protection and communication.

## Assessing the nature of evidence

32. The risk manager in conjunction with a senior manager or clinician should take responsibility for assessing what evidence is to hand. This

needs to be done from the point of view of how it might help any future investigation. For example, evidence may include:

- records e.g. notes, letters, drug charts, print outs from monitors and anaesthetic machines taken at the time (N.B. such print outs may be automatically erased after 24 hours)
  - equipment e.g. instruments, syringes and devices
  - clothing including that of patient and staff
  - packaging e.g. from drugs and equipment
  - the scene more generally e.g. a treatment room
  - personal possessions
  - body of a patient
  - photographs of the scene, with time and date
33. Such evidence needs to be safeguarded. However, for example, if equipment needs to be moved for the sake of patient safety then a record should be made of this - including, if necessary, by taking a photograph. This will remain the responsibility of the risk manager in conjunction with a senior manager or clinician.
34. Such an assessment needs to be made even when the original incident(s) took place a long while ago. For example, archived medical records may need to be traced, carefully recovered and stored or batch numbers of drugs traced.

#### Protecting evidence

35. Once evidence has been identified, all efforts need to be taken to protect it. Such steps may include placing a clinical area temporarily 'out of bounds' to staff and patients but for no longer than necessary. Support staff e.g. cleaners and engineers need to be notified too. An identified person - usually the risk manager - needs to take responsibility for holding any such evidence and for safeguarding it. For example, this might include packaging the evidence carefully or

preserving it in a fridge. Receipts should be obtained and a record kept where any evidence - including equipment - that is handed to another agency.

### Communicating

36. A senior member of staff - usually the risk manager - needs to take responsibility for briefing the police and/or the HSE about what evidence is available, where it is, who has had access to it and what efforts have been made to protect it.
37. It is important that the NHS, police and/or HSE work together to keep patients, relatives, injured parties and NHS staff informed and to provide support as appropriate. The organisations should therefore, as far as possible, agree and follow a liaison strategy for each incident. Such a strategy should be agreed at the first meeting of the Incident Coordination Group and as necessary at subsequent meetings.

#### ***Case Study 2***

SL, a 23-year-old patient, had a long history of recurrent, chronic lung infections and severe asthma. He also had a psychiatric history, which included several overdoses and a history of cutting himself. He had been admitted several times to both psychiatric and general hospitals for his mental health problems and his chronic lung infection.

SL was cared for in a side room on a respiratory ward and was more or less self-caring. He administered a nebuliser and his regular medications were kept in a patient bedside medication locker. One afternoon his primary nurse went to check him and found him dead in bed. He had a 10ml syringe attached to his intravenous line and there was an empty medicine bottle next to his bed.

The nurse immediately instigated the crash procedures. The crash team noted that the circumstances of death seemed unusual. SL's history of taking overdoses was noted and that there was an empty medicine bottle next to him. The staff disturbed as little as possible. Intravenous lines were kept in situ and everyone made sure not to disturb the scene which included furniture, clothes, bed linen, medicine bottles and packaging as well as disposable items.

The senior manager was called and after discussion with the trust board lead for patient safety and the crash team, police were called.

The senior manager instigated the serious incident procedure, secured the patient's clinical notes, put the side room out of bounds and prevented unauthorised people from entering the patient's room.

The senior manager was designated to take the lead and acted as the coordinator for liaising and briefing the police.

Police assessed the evidence, interviewed staff and read the patient's clinical notes. They police decided that there had been no foul play. The case was referred to the coroner.

***Points to note:***

- ***The crash team preserved all evidence and safeguarded the scene.***
- ***Senior management in the trust were notified.***
- ***The senior manager followed the serious incident procedure and took the lead by acting as co-ordinator between the NHS and police.***

## Action once an incident involves the police and/or HSE

### Calling an Incident Coordination Group (ICG)

38. An Incident Coordination Group will be held to discuss patient safety incidents involving either the police and/or the HSE. This meeting can be initiated by any of the agencies. However the NHS has responsibility for the organisation and administration of the meeting. The meeting of the Incident Coordination Group should be called as soon as practicable following the referral and, in any case, the group should meet within five working days of the referral.

### Preparing for the first meeting of the Incident Coordination Group

39. The NHS should prepare for the meeting of the Incident Coordination Group. Matters to consider include:

- patient safety
- information to be shared at the meeting, including matters of confidentiality
- caring for patients, relatives and staff affected
- need for legal advice
- timescales for action and circulating notes etc

40 It is important to agree who is going to attend the first meeting and, if necessary, to ensure that legal advisers are present.

### Conduct & management of the Incident Coordination Group

41. The purpose of the Incident Coordination Group is to provide strategic oversight of a patient safety incident. It is a forum for communicating, exchanging information and coordinating multiple investigations. It allows all the relevant organisations to set out their needs so that actions can be agreed that do not prejudice the work of each

organisation. It is at this meeting that the decision will be made about further investigation, if any, and who will be the lead agency. The NHS will need to raise any issues relating to patient safety at this meeting and set out its views on further action needed to ensure that patients are not at risk.

42. **The Incident Coordination Group has no role in directing the investigations of the NHS, police and/or HSE.**

#### Who should attend on behalf of the NHS

43. Given the importance of the matters to be discussed, those who attend on behalf of the NHS ought to be sufficiently senior to understand the wider implications of the safety incident. They also ought to be able to make decisions and commit resources. Ideally, NHS representation should be at chief executive or executive director level, and also include the risk manager or equivalent. It may also be necessary to ask legal advisers to attend as well as the Caldicott Guardian.
44. In the event of an NHS organisation being a possible future defendant in criminal proceedings, NHS membership of the Incident Coordination Group will need to be discussed with the police and HSE. This will include circumstances where consideration is or may be given to the investigation of an offence(s) under the Health and Safety at Work Act (1974) or those including corporate manslaughter. NHS organisations may need to consider whether they should cede NHS representation to either the local primary care trust or the responsible strategic health authority and then discuss this with the police/ HSE. In the case of foundation NHS organisations this should be Monitor. This consideration applies particularly to investigations involving the HSE, as the duty holder in these investigations is the NHS organisation concerned. However, each case should be considered on its individual circumstances, both in the interests of efficiency and to ensure that patient safety is best safeguarded.

## What should be discussed

The Incident Coordination Group should discuss the following

<b>What should be discussed</b>	<b>What to consider</b>
Nature of the incident(s)	<ul style="list-style-type: none"><li>• What has happened, when and how?</li><li>• Who is involved?</li></ul>
Reasons for meeting, including an explanation from the organisation responsible for calling the meeting	<ul style="list-style-type: none"><li>• Why has the meeting been called? Are other parties involved e.g. relatives, the coroner?</li></ul>
NHS actions to date, including the outcome of any internal or external investigation or root cause analysis	<ul style="list-style-type: none"><li>• What has the NHS done to date? Are written reports available?</li></ul>
Public safety concerns	<ul style="list-style-type: none"><li>• Does the matter raise such concerns?</li><li>• If so, what are they?</li></ul>
Safety of NHS systems and the need for continuity of patient care	<ul style="list-style-type: none"><li>• Is there a need for remedial action and/ or further investigation by the NHS?</li><li>• Does the matter need to be reported to another investigative body e.g. MHRA?</li></ul>
The extent of further, immediate NHS investigations and how these may need to be constrained in subject matter or format by the needs and requirements of the police and/or HSE	<ul style="list-style-type: none"><li>• Is patient safety at risk?</li><li>• If so, what has to be done to minimize this risk?</li></ul>
Role and responsibilities of the police and/or HSE and next steps to be taken (except where this would jeopardise any police/HSE investigations or subsequent legal proceedings)	<ul style="list-style-type: none"><li>• Each organisation should describe what it needs to do next and how it will fit - or conflict - with what others propose to do</li></ul>

Other statutory responsibilities	<ul style="list-style-type: none"> <li>• Do the organisations have other statutory responsibilities they should consider e.g. the need to involve the Local Safeguarding Children Board (LSCB) in a case concerning a child?</li> </ul>
Need to inform professional regulatory bodies e.g. General Medical Council, General Dental Council, Nursing and Midwifery Council	<ul style="list-style-type: none"> <li>• Does the individual(s) need to be reported?</li> <li>• Who will do this?</li> <li>• Should they be excluded? (see NPSA Incident Decision Tree)</li> </ul>
Securing and preserving evidence	<ul style="list-style-type: none"> <li>• Has this been done?</li> <li>• By whom?</li> <li>• What has been preserved?</li> <li>• Where is it?</li> </ul>
Sharing information	<ul style="list-style-type: none"> <li>• What information is available?</li> <li>• What can be shared?</li> <li>• Is consent needed?</li> <li>• To keep patient and relations informed</li> </ul>
Needs of and support to patients, relatives and NHS staff	<ul style="list-style-type: none"> <li>• How are these to be met?</li> <li>• By whom?</li> </ul>
Information to other interested parties e.g. the coroner	<ul style="list-style-type: none"> <li>• Who else needs to know?</li> <li>• What can they be told?</li> </ul>
Handling communications/media	<ul style="list-style-type: none"> <li>• Is the incident likely to attract the attention of the media?</li> <li>• What will be said in response?</li> <li>• Who will say it and in what circumstances?</li> </ul>

<p>Future handling and coordination, including the appointment of a liaison officer from each organisation.</p>	<ul style="list-style-type: none"> <li>• Who from each organisation is to act as point of contact and lead?</li> </ul>
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What should be recorded

45. A detailed written record should be made of the proceedings of the Incident Coordination Group. The NHS should make this official record. These notes should be made contemporaneously and record the matters discussed, the actions agreed and the names of the responsible officers. Timescales should be agreed for actions and these should be recorded. The written record of the Incident Coordination Group should be circulated as soon as possible after the meetings. A completed action plan setting out what is to be done, by whom and by when, should be included with the written record.

Future meetings of the Incident Coordination Group

46. The need for future meetings of the Incident Coordination Group should be agreed at the first meeting. Where it is agreed that the group needs to convene again, the NHS should take responsibility for arranging this. The timescale for these meetings needs to be agreed at the first meeting.

Documents to aid the meeting

47. Suggested terms of reference for the Incident Coordination Group including a model for an outline agenda, tracking pro forma for action agreed are to be found at appendix D to G. They are also available in Word format on the Department of Health website ([www.dh.gov.uk/consultations](http://www.dh.gov.uk/consultations)).

## Sharing information

48. For the NHS, any decision to share or withhold information should be in line with the Department of Health's *Confidentiality: NHS Code of Practice (November 2003) Confidentiality Code of practice*. The code of practice is a guide of required practice for those who work within or under contract to NHS organisations concerning confidentiality and patients' consent in relation to their health records. It is a source of guidance for NHS managers and staff and should be to hand at any meeting of the Incident Coordination Group.

Available at:

[http://www.dh.gov.uk/PublicationsAndStatistics/Publications/PublicationsPolicyAndGuidance/PublicationsPolicyAndGuidanceArticle/fs/en?CONTENT\\_ID=4069253&chk=jftKB%2B](http://www.dh.gov.uk/PublicationsAndStatistics/Publications/PublicationsPolicyAndGuidance/PublicationsPolicyAndGuidanceArticle/fs/en?CONTENT_ID=4069253&chk=jftKB%2B)

- Pages 1 to 10 of the code provide a summary of the key confidentiality issues.
- Pages 33 and 34 provide specific guidance about common law and disclosure in the public interest or to protect the public. Also included are examples of disclosure to protect the public including in the circumstances of serious crime, risk of harm and national security.
- Paragraphs 30 and 31 (page 34) have direct relevance to the sort of issues an Incident Coordination Group may be considering. They say:

*'Under common law, staff are permitted to disclose personal information in order to prevent and support the detection, investigation and punishment of serious crime and/or to prevent abuse or serious harm to others where they judge, on a case by case basis, that the public good that would be achieved by the disclosure outweighs both the obligation of confidentiality*

to the individual patient concerned and the broader public interest in the provision of a confidential service ( [www.dh.gov.uk](http://www.dh.gov.uk)).

*Whoever authorises disclosure must make a record of any such circumstances, so that there is clear evidence of the reasoning used and the circumstances prevailing. Disclosures in the public interest should also be proportionate and be limited to relevant details. It may be necessary to justify such disclosures to the courts or to regulatory bodies. A clear record of the decision-making process and the advice sought is in the interest of both staff and the organisations they work within.'*

49. Where there are concerns about what information to share, legal advice should be sought. ***However, NHS organisations are encouraged to co-operate as fully as possible in the investigation by other agencies of serious incidents.***

#### Supporting patients and relatives

50. In the case of serious incidents leading to the death of a patient, the bereaved people should have access to the information and support they need, including specialist support or counselling services where appropriate. The Department of Health has issued generic advice on developing services to support bereaved families, *When a patient dies: Advice on developing bereavement services in the NHS.*

Available at:

[http://www.dh.gov.uk/PublicationsAndStatistics/Publications/PublicationsPolicyAndGuidance/PublicationsPolicyAndGuidanceArticle/fs/en?CONTENT\\_ID=4122191&chk=qAmlhT](http://www.dh.gov.uk/PublicationsAndStatistics/Publications/PublicationsPolicyAndGuidance/PublicationsPolicyAndGuidanceArticle/fs/en?CONTENT_ID=4122191&chk=qAmlhT)

51. Clearly, in deaths resulting from patient safety incidents, there is likely to be additional anxiety and distress for relatives. Liaison with other agencies, such as police family liaison offers - when such have been appointed to the investigation by the senior investigation officer and coroners' officers, will be particularly important, so that relatives are given accurate and consistent information about what is happening (for

example, the process involved where a coroner's post-mortem and/or inquest is necessary).

### **Case study 3**

XY was a nine-year-old child who had an operation on a finger after he hurt it playing in the garden.

He was given a general anaesthetic and ventilation was started using a Laryngeal Mask Airway (LMA). It then became apparent that he was not responding correctly.

As the emergency situation progressed, all items of the patient breathing circuit (PBC) were changed except the angle connector. Attention was directed towards possible medical conditions. This went on for some time.

A specialist registrar was asked to help and eventually checked the PBC, taking it apart and re-connecting it but by then XY had stopped breathing.

The registrar subsequently discovered that there was a disposable protective cap from an intravenous (IV) giving set blocking the angle connector in the PBC.

XY's death was reported to the coroner, who referred it to the police.

#### ***Points to note***

Referral was made from the coroner to the police in this event, because there was a similarity between this incident and one that had occurred elsewhere three months earlier.

### **Supporting NHS staff**

52. Patient safety incidents and the ensuing investigation(s) have a considerable effect on the staff involved. Appropriate and timely support should be made available to them. This may include professional counselling.
53. Those involved in an incident should be encouraged to contact their professional association and/or union representative. Legal advice for those involved, including witnesses, should usually be provided through professional associations and/or unions rather than by NHS organisation solicitors. In the case of staff that do not belong to a professional

association or union, it may be appropriate for the NHS organisation to consider funding independent legal advice for them.

54. Decisions about the exclusion of staff should be informed by the use of the National Patient Safety Agency Incident Decision Tree which can be found at <http://www.npsa.nhs.uk>. Exclusions should be handled in accordance with the Department of health's framework - *Maintaining High professional Standards in the Modern NHS* - which can be found on the Department of Health website.

#### Handling communications

55. Where possible, the NHS, the police and the HSE should take a common approach to communications particularly to the media. A communications working group should be established involving representatives from all agencies involved and reporting to the Incident Co-ordination Group.
56. The following are some practical suggestions to spur the work of the group:
  - Inform the patient / family before the media.
  - Agree as far as possible what has happened so far and what is going to happen. A good way of getting people to commit to this is to write a bullet-point description of the problem, which explains the incident as a journalist would understand it. It must not, of course, contain any inaccuracies or divulge personal clinical information without consent. It should seek to anticipate the most likely questions but does not need to include every point that may be raised. If parts of the description are disputed or subject to inquiry or legal proceedings then any statement should make that clear and explain the process.
  - Decide on the key messages - try to keep them to three at most and make them relevant and concise.

- Set out a list of what the organisations did in response to the incident and if practices or procedures have already been changed since the incident took place, list those changes. This all helps to put the incident in context and look to the future.
- Say what is being done to prevent recurrence.
- Agree a holding statement for the media and keep this under constant review.
- Seek legal advice on holding statement.
  
- Share media contacts and decide who will talk to each media - speak with one voice where possible and issue joint statements.

All communications should:

- Meet the highest standards of accountability and transparency in public services
- Ensure legality
- Send out messages about public safety showing a determination to learn lessons and improve services where necessary.

## Definitions of key terms relating to offences

### Gross negligence

This is a concept which arises in the common law offence of manslaughter - see "gross negligence manslaughter" below

### Recklessness

In very broad terms, "recklessness" in a criminal law context is where a person takes an unjustified risk.

### Manslaughter

Like murder, the offence of manslaughter involves a killing of a person. The difference between murder and manslaughter is the mental element necessary to support the charge. Manslaughter may be classified as voluntary or involuntary.

### Voluntary manslaughter

This offence is committed where a person has, as in murder, an intention to kill or an intention to cause grievous bodily harm, but he kills under provocation, suffering from diminished responsibility by reason of abnormality of mind or in pursuance of a suicide pact.

### Involuntary manslaughter

This offence is committed a) where death results from an unlawful act which any reasonable person would recognise as likely to expose another to serious risk of injury, and b) where death is caused by a reckless or grossly negligent act or omission (See Halsbury's Laws of England, Fourth Edition, Volume 11(1), paragraph. 426 and the 2005 Cumulative Supplement Part 1). Clarification of these terms is given below.

## **Gross negligence manslaughter**

This offence is committed when a person who owes a duty of care to another, breaches that duty of care and this leads to the death of the other person and the conduct of the person who owes duty of care is considered to be so bad as to be criminal.

There is a four-stage test (the Adomako test) for gross negligence manslaughter.

- The existence of a duty of care to the deceased
- A breach of that duty of care
- Causing the death of the victim
- Whether that duty should be characterised as gross negligence and therefore a crime

## **The Standard and the Breach**

The ordinary law of negligence applies but a higher degree of negligence is necessary to render a person guilty of manslaughter than to establish civil liability against him. Those with a duty of care must act as the reasonable man would do in their position. If they fail to do so, they will have breached their duty of care. The test is objective. In a medical context, the standard of the duty of care owed is that of the ordinary skilled man exercising and professing to have that special skill but it must be remembered that there may be more than one proper standard so that a doctor will not be negligent if he has acted in accordance with a practice accepted as proper by a responsible body of medical men skilled in that art.

### ***The Adomako Case***

The defendant was the anaesthetist during an eye operation on a patient. In the course of the operation the tube from the ventilator supplying oxygen to the patient became disconnected. The patient suffered a cardiac arrest some nine minutes after the disconnection but the anaesthetist failed to notice the disconnection until after resuscitation procedures had commenced, despite an alarm sounding to indicate that the patient's blood pressure had dropped. The defendant was found guilty of gross negligence manslaughter; the Court of Appeal upheld the conviction and the House of Lords approved the four-stage test for gross negligence manslaughter outlined above.

### **Killing with subjective recklessness as to death or serious bodily harm**

A person is subjectively reckless as to a risk of death or serious bodily harm if he himself foresees that risk as a highly probable consequence of his conduct, he takes that risk and in all the circumstances it is unreasonable for him to do so.

### **Corporate manslaughter**

Corporate manslaughter is gross negligence manslaughter committed by a corporation. The same tests apply as for individual gross negligence manslaughter and in order for a corporation to be convicted of gross negligence manslaughter, an identifiable individual's conduct, which can be characterised as gross negligence, must be able to be attributed to the corporation (i.e. an individual who is a "directing mind" at the top of the company must themselves be guilty of gross negligence manslaughter). The conduct of the corporation itself through, for example, poor strategic planning or system failure, cannot lead to a conviction for gross negligence manslaughter. However the position may change in the future with the introduction of the Government's bill on corporate killing.

### Roles, responsibilities and working practices of the police and the HSE

#### *Police*

ACPO (Association of Chief Police Officers)

0207 227 3400

[www.acpo.police.uk](http://www.acpo.police.uk)

The purpose of the police service is to uphold the law and reassure communities by maintaining public order, detecting crime and by reducing crime and the fear of crime. The police will seek to safeguard the rights of all citizens in carrying out their work.

The police service must record all allegations of crime and conduct professional, high-quality investigations, particularly of those crimes that cause widespread public concern in discharging their responsibilities. They must also maintain the security and integrity of all information and intelligence which come within their possession and control.

Patient safety incidents are likely to come to the attention of the police through various means including: referral to the police by the NHS, a complaint directly to the police from families and relatives and a referral from a coroner. The police have a duty to investigate complaints as well as referrals made to them by the coroner.

The police officer who leads an investigation into an incident will usually be a detective of inspector grade or above. The police officer with overall responsibility for the investigation is called the SIO (senior investigating officer). In carrying out their investigation, the police will be seeking to come to an early decision about the following:

- Whether a crime has been committed?
- If so, whether the crime is by an individual(s) or whether it results from corporate failure

In discharging these responsibilities, the senior investigating officer will want to:

- Obtain statements from all those involved
- Secure and preserve evidence
- Decide whether other investigating bodies should be notified e.g. the Health & Safety Executive or MHRA - if not already notified by the NHS
- Obtain expert advice where appropriate

Appoint a family liaison officer to deal with and to provide support to relatives where appropriate.

In cases of death, the senior investigating officer may also be acting on behalf of the coroner. That is, the police will also be seeking to determine the cause of death.

## Health & Safety Executive

0845 345 0055

[www.hse.gov.uk](http://www.hse.gov.uk)

The HSE is responsible for the enforcement of the Health & Safety at Work Act 1974 (HSWA) throughout Great Britain. Its work includes ensuring that 'risks to people's health and safety from work activities are properly controlled'. The HSWA sets out the general duties which employers, the self-employed and people in control of premises have towards their employees and others who could be affected by work activities. The HSE is responsible for enforcing work-related health and safety legislation in a large variety of settings including NHS organisations, other hospitals and nursing homes.

One aspect of the HSE's work is the investigation of incidents within NHS organisations where there is evidence or suspicion of a breach of the HSWA or of regulations made under the Act. Unexpected deaths and/or incidents resulting in serious untoward harm to patients may need to be reported by NHS organisations to the HSE under the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995 (RIDDOR). Accidents to patients that arise from medical treatment or diagnosis are exempt from this requirement. HSE does not investigate all accidents but it will normally investigate all fatal accidents reported under RIDDOR.

Further advice should be sought from the HSE's Incident Contact Centre on 0151 922 9235 in the first instance or reference can be made to the HSE or RIDDOR website ([www.riddor.gov.uk](http://www.riddor.gov.uk)) and a RIDDOR reporting form (F2508) can be filled out and submitted online.

Such incidents may also be referred to the HSE by the police or via the coroner. In all these circumstances a criminal investigation may be launched by the HSE and this will be conducted according to the Memorandum of Understanding to which these guidelines refer.

### Other (relevant organisations), their role and website address

#### ***The Coroner***

[www.coroner.org.uk](http://www.coroner.org.uk)

Coroners are independent judicial officers. They inquire into deaths reported to them which appear to be violent, unnatural or of sudden and unknown cause. If they have reasonable grounds to suspect that a cause of death may have been contributed to or aggravated by negligence, they are required to treat this as potentially unnatural.

#### ***Counter Fraud and Security Management Service (CFSMS)***

[www.cfsms.nhs.uk](http://www.cfsms.nhs.uk)

020 7895 4500

The Counter Fraud and Security Management Service (CFSMS) is division of the NHS Business Service Authority (a Special Health Authority) which has responsibility for all policy and operational matters relating to the prevention, detection and investigation of fraud and corruption and the management of security in the National Health Service.

#### ***Crown Prosecution Service***

0207 796 8000

[www.cps.gov.uk](http://www.cps.gov.uk)

The Crown Prosecution Service (CPS) was created by the Prosecution of Offences Act 1985, and is an independent body that works closely with the police. It is headed by the Director of Public Prosecutions (DPP).

The Crown Prosecution Service is the Government Department responsible for prosecuting those charged with a criminal offence in England and Wales.

As the principal prosecuting authority in England and Wales, it is responsible for:

- Advising the police on cases for possible prosecution.
- Reviewing cases submitted by the police.
- Selecting (in most cases) the appropriate charge.
- Preparing cases for court.
- Presentation of cases at court.

The role of the Service is to prosecute cases firmly and fairly, with impartiality and integrity when there is sufficient evidence to provide a realistic prospect of conviction and when it is in the public interest to do so.

- The CPS does not investigate offences.
- The police contact the CPS during or after an investigation, either to seek legal advice or to refer the case for prosecution.
- Patient safety incidents may be referred to the CPS by the police in such circumstances. There is no need to notify the CPS of a patient safety incident otherwise.

### ***General Dental Council***

020 7887 3800

[www.gdc-uk.org](http://www.gdc-uk.org)

The General Dental Council is the organisation which regulates the dental profession in the United Kingdom. All dentists, dental hygienists and dental therapists must be registered with them to work in the UK.

## ***General Medical Council***

020 7580 7642

[www.gmc-uk.org](http://www.gmc-uk.org)

The GMC is a statutory body responsible for regulating the medical profession in the United Kingdom. It does this by maintaining a register of doctors who are competent and fit to practise medicine.

The GMC's legal authority is the 1983 Medical Act, which gives it strong and effective legal powers designed to maintain standards the public have a right to expect of doctors.

## ***Healthcare Commission***

0845 601 3012 (Investigations)

[www.healthcarecommission.org.uk](http://www.healthcarecommission.org.uk)

The Healthcare Commission exists to promote improvement in the quality of both the NHS and private and voluntary healthcare across England and Wales.

The Healthcare Commission's legal name is the Commission for Healthcare Audit and Inspection. It was established by the Health and Social Care (Community Health and Standards) Act 2003 and launched on April 1st 2004.

The Healthcare Commission would expect to be notified of serious failings (actual or alleged) which may have a negative impact on the safety of patients, clinical effectiveness or responsiveness to patients.

## ***Health Protection Agency***

01235 831600

[www.hpa.org.uk](http://www.hpa.org.uk)

The Health Protection Agency is an independent body established to protect the health and well-being of everyone in England and Wales. The Agency plays a critical role in protecting people from infectious diseases and in preventing harm when hazards involving chemicals, poisons or radiation occur. The agency also

prepares for new and emerging threats, such as a bio-terrorist attack or virulent new strain of disease.

### ***Medicines and Healthcare Products Regulatory Agency***

020 7273 0000  
[www.mhra.gov.uk](http://www.mhra.gov.uk)

From 1 April 2003, the Medicines and Healthcare products Regulatory Agency (MHRA) replaced the Medical Devices Agency (MDA) and the Medicines Control Agency (MCA). The MHRA is an Executive Agency of the Department of Health with trading fund status. It is the Competent Authority for medical devices and the Licensing Authority for pharmaceuticals.

### **Monitor [Independent regulator of NHS Foundation Trusts]**

020 7340 2400  
[www.monitor-nhsft.gov.uk](http://www.monitor-nhsft.gov.uk)

Monitor is an independent corporate body established under the Health and Social Care (Community Health and Standards) Act 2003. It is responsible for authorising, monitoring and regulating NHS Foundation Trusts.

Once NHS Foundation Trusts are established, it monitor their activities to ensure that they comply with the requirements of their terms of authorisation. Inspection of the performance of a foundation trust against healthcare standards is carried out by the Healthcare Commission. Monitor have powers to intervene in the running of a foundation trust in the event of failings in its healthcare standards or other aspects of its activities, which amount to a significant breach in the terms of its authorisation.

### ***NHS Litigation Authority***

020 7430 8700  
www.nhsla.com

The NHSLA is a Special Health Authority (part of the NHS), responsible for handling negligence claims made against NHS bodies in England. In addition to dealing with claims when they arise, it has an active risk-management programme to help raise standards of care in the NHS and hence reduce the number of incidents leading to claims. It also monitors human rights case-law on behalf of the NHS through its Human Rights Act Information Service.

### ***Nursing & Midwifery Council***

0207 637 7181  
www.nmc-uk.org

The core function of the Nursing & Midwifery Council (NMC) is to establish and improve standards of nursing, midwifery and health visiting care in order to serve and protect the public.

### ***National Patient Safety Agency (NPSA)***

020 7927 9500  
www.npsa.nhs.uk

The NPSA is a Special Health Authority created following the publication of two reports on patient safety in the NHS *An Organisation with a Memory* (Department of Health, 2000), and its follow-up *Building a Safer NHS for Patients* (Department of Health, 2001). The NCAS, (previously the NCAA) and NHS Estates, are now divisions of the NPSA.

#### NHS Estates

0113 254 7000  
www.nhsestates.gov.uk

The NPSA assumed responsibility for specific safety aspects of hospital design, nutrition and hygiene from NHS estates.

#### National Clinical Assessment Service

0870 267 0850  
www.ncas.npsa.nhs.uk

The NCAS provides a service to support the NHS deal with doctors and dentists whose performance gives cause for concern. It aims to provide advice about the local handling of cases, and where necessary carry out clinical performance assessments to clarify areas of concern and make recommendations on how difficulties may be resolved.

***SHOT (Serious Hazards of Transfusion)***

0161 251 4208

[www.shotuk.org](http://www.shotuk.org)

The Serious Hazards of Transfusion (SHOT) Scheme collects data on serious hazards of transfusion of blood components. Through the participating bodies, the information obtained contributes to: improving the safety of the transfusion process; informing policy within the Transfusion Services; improving standards of hospital transfusion practice; aiding production of clinical guidelines for the use of blood components.

Health Service Circular HSC1998/224 instructed all NHS organisations where blood is transfused to participate in SHOT reporting from March 1999. This instruction was reiterated in HSC2002/009. EU legislation which was enshrined in UK law in 2005 will now make it a legal requirement for serious adverse events and serious adverse reactions relating to blood transfusion to be reported to a Competent Authority.

## Appendix D

### Incident Coordination Group - Terms of Reference

The Incident Coordination Group is a multi-agency group convened at the request of the NHS, police or HSE. The purpose of the Incident Coordination Group is to provide strategic oversight of a patient safety incident involving the NHS and the police and/or HSE. It is a forum for communicating, exchanging information and coordinating multiple investigations. Its role is to :

1. Ensure that any further investigations are appropriately coordinated and that NHS investigations do not impede or prejudice police and/or HSE investigations.
2. Ensure that other statutory responsibilities are acted on e.g. safeguarding children
3. Where possible, prepare a single media-handling plan.

***The Incident Coordination Group has no role in directing the investigations of the police and/or the HSE.***

In conducting its work the Incident Coordination Group will want to discuss the issues outlined in the table on page 15.

Responsibility for organising and administrating the Incident Coordination Group meetings rests with the NHS. This responsibility includes making and circulating a record of the meeting, including the actions agreed.

The NHS should chair the first meeting of the group unless the circumstances preclude this.

## Model agenda for the Incident Coordination Group

### General details of initial meeting

*This agenda gives a general overview of items to discuss at ICG meeting*

- Date of first ICG meeting
- Chaired by
- Date of incident
- Nature of incident
- Immediate action taken
- Name of coroner, if applicable
- Name of NHS staff and others involved in incident
- Name of NHS organisation/police force/HSE office
- Name and details of patients and relatives
- Brief narrative description of meeting - including matters and actions agreed

Model agenda for recording decisions

Record of decisions of meeting and further actions (Outcome)

Date	
Decision of ICG	
Action agreed	
Who to action/which organisation	
Date of next meeting	

## Tracking form

## Immediate action following an incident

1. Can the patient safety incident be investigated using existing NHS procedures developed by the Department of Health and NPSA?	Yes	No
2. Does the incident need to be reported by the NHS organisation to other health related organisations?	Yes	No
3. Has the NHS organisation <i>informed</i> the organisations with an analytical or advisory function, e.g. DH or NPSA?	Yes	No
4. Has the NHS organisation sought <i>advice</i> from the DH's Patient Safety & Investigation Branch and / or the Healthcare Commission?	Yes	No
5. Has the NHS organisation considered whether the incident needs to be reported to the police and / or HSE?	Yes	No
6. Has the NHS organisation's risk manager or equivalent made early, informal contact with the police and HSE to discuss concerns or take advice about further action?	Yes	No
7. Does the unexpected death or patient safety incident need to be reported to the HSE under RIDDOR?	Yes	No
8. Has the question of reporting the patient safety incident to the HSE been discussed with the risk manager or equivalent?	Yes	No
9. Has the risk manager preserved all relevant evidence and safeguarded the scene?	Yes	No
10. Has the risk manager assisted the senior manager / clinician in assessing the evidence?	Yes	No
11. Has a record been made regarding movement of equipment, e.g. have photographs of the scene been taken?	Yes	No
12. Has the risk manager protected the evidence by packaging and preserving it?	Yes	No

## Incident Co-ordination Group and evidence

13. After reporting to police, has an agreement been reached about whether or how the ICG should be conducted?	Yes	No
14. Has the possibility of a joint investigation been considered at the ICG?	Yes	No
15. Have further steps been taken to secure and preserve evidence?	Yes	No
16. Does older evidence need to be traced, such as archived records and drug batch numbers?	Yes	No
17. Have receipts been obtained and records kept where evidence has been handed to another agency?	Yes	No
18. Has the risk manager continued briefing the police and HSE regarding the status of the evidence?	Yes	No
19. Has a representative from the NHS organisation taken responsibility for organizing and administrating the ICG meeting?	Yes	No
20. Has it been agreed who is to attend the first meeting, and when necessary, ensured that legal advisors are present?	Yes	No
21. Will further investigation be necessary, and if so, which will be the lead agency?	Yes	No
22. Is the NHS representative at chief executive or at executive director level?	Yes	No
23. From discussions at the ICG, does the NHS organisation need to cede representation to the local PCT or SHA?	Yes	No
24. Has a detailed written record been made of the proceedings of the ICG?	Yes	No
25. Has it been agreed when the ICG group should convene again, and how regularly?	Yes	No

## Supporting staff and relatives

26. Has appropriate and timely support been made available to family and NHS staff involved, including professional counselling?	Yes	No
27. Have the staff been encouraged to contact their professional association and union rep?	Yes	No
28. Has legal advice been provided through the professional association or union?	Yes	No
29. Has a communications working group from all agencies been established?	Yes	No
30. Has the NHS organisation ensured that the family have been informed before the media?	Yes	No